

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

### Device Name:

Proprietary Name:	Stryker Ureteral Illumination System IV
Common and Usual Name:	Stryker Universal Ureteral Kit or Stryker Universal U-Kit or Stryker Ureteral Illumination System IV or Fiberoptic light ureteral catheters
Classification Name:	Fiberoptic light ureteral catheter (Class II, 876.4020, Product Code FCS, Gastroenterology-Urology Devices Panel)

The Stryker Ureteral Illumination System IV with the InfraVision IR Illuminator is intended to transluminate the ureter during surgical procedures. The Catheter accepts up to a 0.038" guidewire. The Kit can be used for either open surgical (with the InfraVision Detector Probe) or laparoscopic (with the InfraVision Camera) access.

The Stryker Ureteral Illumination System IV consists of an open-ended ureteral catheter, which allows the use of a guidewire (up to 0.038" dia), is composed of Pellethane™ with a hydrophilic coating to ease insertion into the ureters and incorporates a fiberoptic light guide that is used with the InfraVision IR Illuminator to transluminate the ureter during surgical procedures. It can be used for either open surgical or laparoscopic access and is distributed as a sterile, single use disposable product. The device is validated for EtO sterilization to a SAL of  $10^{-6}$ .

The Stryker Ureteral Illumination System IV is substantially equivalent in terms of safety and effectiveness to the currently marketed Stryker Ureteral Illuminator System III (ref: K982542). The Stryker Universal U-Kit will conform to the following voluntary safety and performance standards: ISO 10993, Blue Book Memorandum G95-1, ANSI/AAMI/ISO 11135, EN 550, ASTM D4169, ASTM D999, ASTM D1140, ASTM D4332, ASTM D4728, ASTM D5276, ASTM F88, EN 868-1, ISO 11607, and FPA SPMC 005-96.

The technological differences between the Stryker Ureteral Illumination System IV and the identified predicate devices (Stryker Ureteral Illuminator System III, K982542) do not affect the safety and efficacy of the product; therefore, the Stryker Ureteral Illumination System IV is substantially equivalent to the identified predicate devices.

By: Erica A. Walters

Date: 8.28.06

Erica A. Walters  
Sr. Regulatory Representative  
Stryker Endoscopy



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

SEP 28 2006

Ms. Erica A. Walters  
Sr. Regulatory Representative  
Stryker Endoscopy  
5900 Optical Court  
SAN JOSE CA 95138

Re: K061548  
Trade/Device Name: Stryker Ureteral Illumination System IV  
Regulation Number: 21 CFR §876.4020  
Regulation Name: Fiberoptic light ureteral catheter  
Regulatory Class: II  
Product Code: FCS  
Dated: August 28, 2006  
Received: August 30, 2006

Dear Ms. Walters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

Device Name: Stryker Ureteral Illumination System IV

Indications for Use:

The InfraVision Ureteral Kit with the InfraVision IR Illuminator is intended to transilluminate the ureter during surgical procedures. The Catheter accepts up to a 0.038" guidewire. The Kit can be used for either open surgical (with the InfraVision Detector Probe) or laparoscopic (with the InfraVision Camera) access.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number X061548